REMARKS

This Amendment is made in response to the Office Action mailed September 14, 1989. A request for a three-month extension of time accompanies this response. Claims 1-91 are pending in this application, although claims 1-6, 9, 12-15 and 17-51 have been withdrawn from consideration by the Examiner.

Applicant once again respectfully traverses the restriction requirement and requests its reconsideration. Applicant additionally requests reconsideration of the withdrawal of claims 1-6, 9, 12-15 and 17-51.

Applicant submits that this invention is applicable for use in any type of hydrodynamic pump and therefore applies equally with axial flow pumps, mixed flow pumps or centrifugal pumps. Moreover, applicant submits that the entire application encompasses one inventive concept, and, accordingly, all the claims should be examined in one application.

Turning now to the action on the merits, the subject matter of the examined claims relates to implantable blood pumps capable of supporting or replacing the function of a diseased natural heart in such a way as to provide a patient with many years of high quality life. The background and objectives of the specification contain considerable detail concerning the requirement that any successful permanent artificial heart must overcome numerous potential problems including significant blood damage, macroscopic thrombosis and infection.

In particular, the present specification, especially page 5, line 15-21, notes:

> "In order to present the lowest risk of infection, artificial heart systems should:
>
> (1) Cause no functional derangements in the immune system via the interaction of mechanical damage to the white blood sells or via other mechanisms.
>
> (2) Permit surgical implantation with minimal bleeding.
>
> (3) Present the minimal surface area of artificial materials to the bloodstream and occupy a minimum volume within the body without excessive surface area.
>
> (4) Be anatomically adapted to fit within the body without causing pressure necrosis of the tissues.
>
> (5) Heal into the body tissues well with close proximity of vascularized tissues in the vicinity of the surface of the artificial heart.
>
> (6) Require no skin penetration unless such a system is a completely effective barrier against the entrance of bacteria."

The present invention is based on a long term study of the interaction of artificial heart mechanisms with the physiologic system and a study of important physiologic interactions. More than 125 U.S. Patents covering blood pumps have been issued and most of these inventions share a number of common features. With the present invention, important major new functional and structural elements are introduced which are not obvious in light of the prior art, and include clearly distinguishable and unique new features. For example, the concept of implanting the entire blood pump within the natural ventricular cavity is entirely new and original. Certain advantages of this invention, including avoidance of infection, are delineated in the disclosure.

Claims 7, 8 and 16 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,625,712, hereafter "Wampler". Applicant respectfully traverses this rejection.

Independent claims 7 and 16 have been amended to require that the blood-pumping elements are configured so that they reside wholly within the natural heart.

The Official Action asserts that "in Figure 1a, the device is seen to be implanted within the ventricle of the heart." However, this represents a misunderstanding of the Wampler patent. Figure 1a clearly identifies the pump which is located in the aorta, above the aortic valve leaflets. Only a cannula is placed within the ventricular cavity; the pump itself is not. Stated in Wampler, column 2, lines 57-60, "the intravascular blood pump 10 of this invention may access the left ventricle 12 (Figure 1a) of the heart 11 by retrograde insertion of an appropriate short flexible inlet cannula 14 through the aortic valve 15."

Many types of blood pumps or cardiac support devices have utilized cannulae which access (remove blood) from the ventricle, either placed across the aortic valve, across the mitral valve, or through the wall of the ventricle itself. In the present invention, the entire blood pumping device (other than the external batteries, electronics, and wires) may be implanted within the ventricular cavity. In Wampler, the components of the blood pump which produce the rotary mechanical force to drive the impeller and thereby pump the blood, are located outside the body

(see no. 28, Fig. 1b) and the rotary power is transmitted by a long, high speed rotary drive shaft through a catheter, across the body wall and through the aorta to the point where the actual impeller of the pump is located. Even if Wampler chose to utilize no inflow catheter and chose to insert the axial flow pump 10 across the aortic value into the ventricle (there is no indication that Wampler ever considered this), Wampler's device would still be fundamentally different from the present invention which requires no external drive shaft. The requirement of Wampler's device for a high speed, rotating "flexible shaft" with a remote motor makes it incapable of application for long term use because the long flexible drive shaft will fracture due to bending stress. The present invention is adapted to function for many years without mechanical failure.

Further, as noted, the claims have been amended to better reflect that the blood-pumping elements utilized in the present invention are configured so that they reside wholly within the natural heart. Nowhere is this taught (or even suggested) by Wampler. Accordingly, the present invention is not anticipated by Wampler, and it is requested that this rejection be withdrawn.

Claim 10 was rejected under 35 U.S.C. 103 as being unpatentable over Wampler. This rejection is also traversed.

Claim 10 is dependent upon claim 7 which, for the above stated reasons, should now be allowable. Additionally, the function of the porous material on the surface of the implant is

indeed to promote tissue ingrowth. However, the purpose of the ingrowth is to minimize infection and not to enhance mechanical stability as suggested in the Office Action. The instant specification clearly discusses the reasons why an adequate blood supply to the area immediately surrounding the outside surface of the artificial heart is effective in preventing infection. The use of porous materials which stimulate the ingrowth of tissue causes new capillaries to be developed. These new capillaries bring additional antibodies and white blood cells to the area to prevent infection. Without tissue ingrowth, a thick, poorly vascularized, scar capsule could develop, and the space between such a scar capsule and the surface of the artificial heart could more readily become infected. Thus, the use of the porous material is important to the unique function of the invention related to the intraventricular placement of the device.

Accordingly, this rejection should be withdrawn.

Claim 11 was rejected under 35 U.S.C. 112, second paragraph, for lacking antecedent basis for an energy converter. Claim 11 has been amended. It is respectfully submitted that this claim is now clear and fully satisfies the requirements of 35 U.S.C. 112. Accordingly, this rejection should be withdrawn.

Claims 52-54, 70-75, 79-81 and 85-91 were rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 3,608,088, hereafter "Dorman". This rejection is respectfully traversed.

Independent claims 52-54 and 85 have been amended to incorporate the antithrombogenic structure of the present

invention into them. These claims now require that the bearings and bearing means be washed by high enough blood flow to prevent thrombus accumulations severe enough to cause failure of the pump.

The Dorman invention gives no consideration to thrombus formation. In fact, no mention whatsoever of thrombus or its avoidance is made in the patent. The structures disclosed and claimed in Dorman are inherently prone to excessive thrombus formation and cannot be modified to avoid this. With the implantable blood pump of Dorman, there is a tendency for blood clots to form in the space between the impeller and the inclined wall of the thrust plate, disposed adjacent to the impeller. The impeller has blades which radiate from a hub in a manner as to leave a relatively large hub surface area adjacent to the thrust plate. Blood lubricates the rotating pump parts and therefore floods the space between the hub and thrust plate. As a result of this pump construction, the flow of blood between the large hub surface area adjacent to the thrust plate tends to be very slow and thereby enhances formation of blood clots. As a direct result of the clot formations between the impeller and the thrust plate, the impeller is forced away from the thrust plate. This draws the magnetic rotor up against the flat, rear face of the thrust plate and results in seizure of the pump.

The present invention recognizes that the avoidance of both excessive blood damage and thrombus in all parts of the pump is crucial to success. This includes avoidance of thrombus related

to the interaction between the rotating and stationary components of the bearings and the adjacent flow. Dorman completely fails to recognize this and fails to provide the necessary configuration of the bearing structure together with high enough blood flow to wash the bearings which is essential to prevent failure due to thrombus formation.

Dorman also isolates the bearing from the pumping chamber containing the impeller. This prevents all but a small amount of blood flow through the gap around the shaft between the first and second chambers. Thus, the blood, generally isolated within the bearing chamber, is rapidly hemolyzed at first. However, thereafter, hemolysis is markedly diminished because little new blood is exposed to the damaging forces of the rotating bearing. Dorman's use of a second chamber is reasonably effective at providing a bearing which is low in hemolysis overall, however, the same structure is unavoidably thrombogenic and causes the failure of the pump. Besides causing the pump to seize up, the thrombus forms a ring around the rotating shaft and is held in position by its extension into the bearing chamber. This provides an anchoring site for thrombus to accumulate behind the impeller hub and, in addition to binding the hub, the thrombus may break loose in large pieces causing thromboembolism and stroke, even before the pump seizes up.

The present invention successfully avoids all these problems. The claims have been amended to clarify the antithrombogenic structure of the present invention. Independent

claims 52-54 and 85 require that the bearings and bearing means be washed by high enough blood flow to prevent thrombus accumulations severe enough to cause failure of the pump. This clearly distinguishes the present invention from Dorman. Failure can be caused by seizure of the rotor (see, for example, the remarks concerning Dorman, supra) and other causes such as blockage of the flow channel by thrombus.

For all these reasons, it is respectfully requested that this rejection over Dorman be withdrawn.

Claims 61-63 were rejected under 35 U.S.C. 103 as being unpatentable over Dorman. This rejection is traversed.

Claims 61-63 depend from claims 52, 53 and 54, which have been shown to be distinct from Dorman. Therefore, claims 61-63 should not be rejected as unpatentable over Dorman. Moreover, these claims add an important limitation of size to the new invention and not merely a limitation of size to Dorman. It is not obvious to design an artificial heart small enough to be implanted within the ventricular cavities of the natural heart. Typically, designing artificial hearts that would fit within the pericardial sac after removal of the natural heart has been recognized as the range of size that a designer of such a device would consider in adapting to the varying size of patients. Miniaturization sufficient for implantation within the ventricular cavities is a new concept for devices which include both an electric motor and a rotary pump.

Accordingly, this rejection should be withdrawn.

Claims 58-60 were rejected under 35 U.S.C. 103 as being unpatentable over Dorman. These claims do not merely add additional structure to Dorman as asserted in the Official Action, but rather, these claims add the control function to the present invention which has already been patentably distinguished from Dorman. Accordingly, this rejection should be withdrawn.

Claims 64-69 and 82-84 were rejected under 35 U.S.C. 103 as being unpatentable over Dorman in view of U.S. Patent No. 4,704,121, hereinafter "Moise". Moise does not teach a drive structure as claimed herein.

Moreover, simply utilizing a drive structure as Moise uses, and combining it with Dorman, would not solve Dorman's fundamental problems. The pump would still be fundamentally thrombogenic because of the second chamber in which the fluid film bearings are located separate from the impeller chamber, and because of the necessity of a drive shaft between the two chambers with the associated thrombogenic gap.

The present invention avoids this catastrophic problem by using very small diameter non-fluid film blood immersed bearings which do not require a second chamber, as Dorman requires.

The rejected claims specify relationships between the size of the components of the device. These claims do not specify absolute sizes, but rather, they express important relationships such as the ratio of the size of the outside diameter of the motor rotor compared to the size of the inside diameter of the motor windings and laminations. These relationships are

apparently neither taught nor suggested by the cited art. Accordingly, it is respectfully submitted that this rejection be withdrawn.

Claims 55-57 and 76-68 were objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Applicant submits that the base claims have been amended and, from the foregoing discussion, are clearly allowable. Therefore dependent claims 55-57 and 76-78 are also allowable and applicant should not be required to write them in independent form. Applicant requests that the objection be withdrawn.

The art cited but not relied upon in the rejection of specific claims has been reviewed but is deemed to be even less pertinent than the art applied with respect to the present claims.

Applicant also submits herewith an Information Disclosure Statement and list of references.

In view of the amendments and all the arguments of record, favorable reconsideration and withdrawal of the restriction

requirement and rejections, favorable consideration of claims 1-91, and especially claims 7, 8, 10, 11, 16, 52-54, 58-75 and 79-91, and allowance of this application are all respectfully requested.

Respectfully submitted,

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